

## REMARKS

### I. Status of the Claims

Claims 1-5, 7-8, 10-21, 23-24, and 28-32 are pending. Claims 6, 9, 12, 22 and 25-27 have been cancelled. Claims 1, 17, 20, 23, and 24 are in independent form. Claims 29-32 are new claims.

Claims 29 and 30 are new dependent claims directed to a preferred embodiment wherein the confectionery product has only one oral comfort region and one salivation region. Support for these claims is found in the specification at paragraph [0031], for example.

Claims 31 and 32 are new dependent claims which recite that the salivation agent is concentrated to promote oral manipulation of the product. Support for these claims is found in the specification at paragraphs [0018] and [0043], for example.

This Amendment is being submitted with a Request for Continued Examination to ensure that Applicants have the opportunity to file one or more additional fact Declarations prior to filing an Appeal Brief.

### II. Rejections Under 35 U.S.C. § 103

1. Claims 1-5, 7-8, 10-11, 13-14, 17, 20, and 23-24 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 5,284,659 (“Cherukuri”) in view of WO 99/579427 (“Le”).

2. Claims 18-19 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Cherukuri in view of Le, further view of U.S. Patent No. 4,517,205 (“Aldrich”).

3. Claims 15-16, 21, and 28 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Cherukuri in view of Le, and further view of U.S. Patent No. 6,004,538 (“Hughes.”)

4. Claims 1-5, 7-8, 13-18, and 23 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,306,429 (“Bealin-Kelly”) in view of WO 97/06695 (“Hanke II”).

5. Claims 20-21 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Bealin-Kelly in view of Hanke II further in view of National Institute of Dental and Craniofacial Research, NIH publication, June 1999.

6. Claim 19 has been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Bealin-Kelly in view of Hanke II further in view of US Patent No. 6,099,880 (“Klacik.”)

### III. Argument

According to the present inventors, at paragraph [0018], “it has been surprisingly discovered that having the salivation agent concentrated in one region of the product enhances the initial salivation effect and promotes mechanical action or movement of the piece throughout the mouth. In particular, because of the separation of the two regions, greater amounts of salivation agent may be used resulting in an increased initial impact causing enhanced oral manipulation, but still with acceptable taste.” This central feature of the present claims, that the claimed product configuration is related to its functionality as a dry-mouth relief product, which has been emphasized in arguments throughout the long pendency of this application, continues to be entirely ignored in formulating the rejections of record.

Acids have been used in the prior art to cause salivation, as described in the present specification in para. [0008], for example. Products have been disclosed in the prior art having discrete regions with a surface on the exterior of the product. However, the use of an oral comfort region and a discrete region containing acid in a product configuration that promotes movement of the candy in the mouth and thereby increases salivation is both novel and non-obvious. It is believed that separating the components in this manner permits the use of a higher concentration of acidulent, causing a greater initial impact resulting in oral manipulation of the product in the mouth.

The rejections applied against the present claims are based on arbitrary combinations of the prior art, and do not make obvious the claimed product configuration, wherein a salivation ingredient and an oral comfort ingredient are provided in discrete regions of a hard candy product, to promote mechanical movement of the piece in a person's mouth, which promotes salivation.

A. Claims 1-5, 7-8, 10-11, 13-14, 17, 20 And 23-24 Are Not Obvious Over Cherukuri and Le

Cherukuri is relied on to show a product having two phases (referred to in the reference as a “shell” and a “core”) in two separate regions. This is depicted in Fig. 6. The shell region contains breath deodorant, and the Office Action maintains that the region may contain other “bio-effecting” agents, including *antigingivitis agents*, and that this region reads on the claimed “salivation region comprising an acidulent in an amount effective to aid in the stimulation of the flow of saliva in an oral cavity. . .” *See Office Action*, page 4 (emphasis in original). Significantly, according to the Office Action, one has to add acidulent, relying on a different reference, to achieve that functionality.

On the other hand, the core region in Cherukuri contains fat encapsulation, which in some embodiments “may be combined with a diluent, lubricant, and/or bonding agent.” (*See* Cherukuri, col. 8, lines 55-65). This region is alleged to read on the claimed “oral comfort region comprising an oral comfort ingredient selected from the group consisting of lipids, surfactants and mixtures thereof in an amount effective to lubricate, coat or moisten said oral cavity.” The diluent is said to read on the confectionery base.

The Office Action argues that it would have been obvious to take acidulent from Le and incorporate it with the diluent in the pressed tablet of Cherukuri on the basis that acidulent is a “bio-effecting agent.” The argument in the Office Action appears to be that Le teaches that acids in chewing gum can soften plaque on teeth. According to the Office Action, because acids can reduce plaque, they are “bio-effecting agents” under the category of “antigingivitis agents.”

However, it is not correct that acids are known to be used as antigingivitis agents. The suitable antigingivitis agents identified in Cherukuri are “chlorhexidine, thymol, menthol, methyl salicylate, eucalyptol and mixtures thereof.” (Cherukuri, col. 7, lines 41-43). None of these are acids. Chlorhexidine and essential oils are well known in the art as antigingivitis agents. See, for example, “Dimensions of Dental Hygiene,” attached as Exhibit A. Acids, on the other hand, are not known as “antigingivitis agents.” In fact, it is likely that acids would be regarded as damaging to tooth enamel, and therefore, would not be recommended for gingivitis prevention. Accordingly, the substitution of an acid taught in Le for a “bio-effecting” agent taught in Cherukuri, on the grounds that an acid is an antigingivitis agent, is not a “reason” to combine the prior art that would be recognized by one of ordinary skill in the art.

It is also not correct that it would have been obvious to substitute a salivation-causing amount of acid in a product configuration of Cherukuri. Significantly, Applicants are not claiming the salivation-causing effect of acid in one region of the product. The claims are directed to a product having discrete regions, with an acid in one region and an oral comfort ingredient in another. The Office Action does not show that an acid according to Le, added to a region in Cherukuri, would be effective to cause oral manipulation of the product to enhance salivation. The Office Action does not show that the opposing region of the Cherukuri product, the region containing the fat encapsulation, would be effective to lubricate, coat or moisten the oral cavity if acidulent were provided concentrated in another discrete region of the product. Therefore, the asserted combination does not read on the claimed product, which has two regions, one containing acidulent, the other containing an oral comfort ingredient.

The Supreme Court has recently abandoned the so-called “teaching-suggestion-motivation” test for determining obviousness. However, a reason for combining the disparate elements in the prior art is still required to make a finding of obviousness. *KSR Int’l Inc. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740-41 (2007). Likewise, it is improper under Supreme Court precedent to use hindsight reasoning, such that the applicant’s disclosure becomes the road map for making the asserted combination of elements. *KSR*, 127 S. Ct. 1742.

There is no teaching in Cherukuri to replace the breath freshener taught in the Examples with Le's acid. Moreover, Le teaches that oxidative acids quickly oxidize acid-sensitive additives such as flavors in a composition (pg. 1, lines 26-28). Therefore, one skilled in the art would have been inclined not to put acid in the shell/rapid release

portion of Cherukuri, which contains flavors. There are, significantly, no acids in Cherukuri's compositions, and it would not have been "obvious" to incorporate them.

According to the claimed invention, the regions have "a surface on the exterior of the product." Therefore, the oral cavity is exposed to the salivation and oral comfort ingredients simultaneously. This is opposite Cherukuri's objective of having different and separate release of flavors from two different regions of a product (initial, rapid release from one region vs. slow, extended-release from another region). For this additional reason, it would not have been obvious to configure a product based on Cherukuri, as alleged, because it would not have achieved the required separate release profiles central to the Cherukuri disclosure.

Finally, the "diluent" described in Cherukuri does not read on a "sugar or sugarless confectionery base," as claimed. (Note that the diluent is distinct from the sweetener, described in Cherukuri col. 9, lines 8-35, and there is clearly no disclosure in Cherukuri of a sugar confectionery base selected from the group consisting of sucrose, glucose, fructose, etc. set forth in claim 3.) These sweeteners are clearly distinguished from the diluents disclosed in Cherukuri. Therefore, Cherukuri does not disclose a sugar or sugarless confectionery base. For this additional reason, even if these disparate references were combined according to the suggestion in the Office Action, they do not read on the present claims, because there is no basis to provide a confectionery base in each of the discrete regions.

B. Claims 18 And 19 Are Not Obvious Over Cherukuri, Le And Aldrich

Cherukuri is directed to compressed tablets (see abstract), and Le is directed to products such as toothpaste and chewing gum (see abstract). Aldrich is

alleged to show the method of making a hard candy recited in claims 18 and 19 (Office Action, page 9). However, one of ordinary skill in the art, starting from the disclosure of Cherukuri and Le, would have not have been directed to formulate a hard candy according to the method of Aldrich, using the ingredients of Cherukuri and Le. Accordingly, Aldrich does not overcome the deficiencies of the primary references.

C. Claims 15-16, 21, And 28 Are Not Obvious Over Cherukuri, Le, And Hughes

Claims 15-16, 21 and 28 require the combination of an acidulent and a cooling compound in the salivation region. The Office Action asserts that it would have been obvious to include a cooling compound in the shell region of Cherukuri because (1) Hughes teaches that menthol is both a flavorant and reduces plaque, (2) Le teaches the use of acids to soften plaque on teeth (Office Action page 10). The rejection plainly relies on hindsight. There is no teaching in the references of an acid and cooling compound used together, and even if they were combined there is no disclosure in the prior art of these ingredients being used together in a salivation region.

D. Claims 1-5, 7-8, 13-18 And 23 Are Not Obvious Over Bealin-Kelly And Hanke II.

Bealin-Kelly teaches a liquid center fill (see Bealin-Kelly, col. 1, line 8), not a hard candy, as presently claimed. Moreover, the entire gist of Bealin Kelly is to provide “sequential release profiles” in two different regions. Therefore, the patent gives good reasons why that product should not be configured with discrete regions having a surface on the exterior of the product (because doing so would tend to cause release of flavors at the same time). Like the secondary reference, Hanke II, Bealin-Kelly is directed to a cough-cold relief lozenge, rather than a xerostomia-relief product. The

Office Action does not even supply a plausible explanation why these references would have been looked at in the context of formulating a dry-mouth relief product. There is simply no appreciation in the Office Action of the relationship between the product configuration and the salivation effect. The reasons for combining the references as alleged are clearly based on hindsight and pretextual, and Applicants respectfully request that the rejection be reconsidered and withdrawn.

E. Claims 20 And 21 Are Not Obvious Over Bealin-Kelly, Hanke II And National Institute of Dental and Craniofacial Research, NIH publication, June 1999

The NIH publication simply teaches that sucking on hard candy provides some relief from dry-mouth. The claimed product is novel and non-obvious for the reasons given above, and its use to treat dry-mouth is likewise non-obvious.

F. Claim 19 Is Not Obvious Over Bealin-Kelly, Hanke II And Klacik

Klacik is not believed to overcome the deficiencies of Bealin-Kelly and Hanke II and therefore Claim 19 should be allowable for the same reasons as argued above in connection with the independent method claim 17.

CONCLUSION

The claims being allowable for the reasons given above, reconsideration on the merits is respectfully requested.



Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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